

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1, 3 and 5-35 are pending in the present application. Claims 12-22 and 29-33 have been withdrawn. Claims 1, 3, 5-11, 23-28 and 34-35 are subject to examination. Applicant has amended claims 1, 3, 5-11 and 23-28 to address several informalities in the claims. In addition, claim 1 has been amended to incorporate the recitations of claims 2 and 4. New claim 35 has been added. Support for claim 35 may be found in original claim 1. Claims 2 and 4 have been canceled.

In the outstanding Official Action, claims 1-11, 23-29 and 34 were rejected under 35 USC 112, first paragraph, for allegedly not satisfying the enablement requirement. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleged that the only way to provide a reasonable expectation of success of practicing the claimed invention was to subject fetal calf serum to a heat treatment between 60°C and 80°C for between 30 minutes and 12 hours (see page 7 of Office Action mailed on December 1, 2004). The Office Action also alleged that while the specification suggests that other times and temperatures are contemplated, the suggestions are insufficient to provide the required amount of predictability and would cause one who would

practice the claimed invention to engage in an undue amount of experimentation to determine which specific combinations of time and temperature would provide a reasonable expectation of success.

However, at this time, the Examiner is respectfully reminded that the determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness having regard to the nature of the invention. The test is not merely quantitative, since a considerable amount of experimentation is permissible, and if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable determination of how to practice a desired embodiment of the invention claimed.

W.L. Gore & Associates, Inc. v. Garlock, 721 F.2d 1540, 220 USPQ 303 (Fed. Circ. 1983); and *In re Rainer*, 146 USPQ 218 (CCPA 1965). Applicant believes that determining the specific combinations of time and temperature would not constitute an undue amount of experimentation to one of ordinary skill in the art. Indeed, the Office Action fails to present evidence to the contrary.

Moreover, upon reviewing the present specification, applicant notes that the present specification teaches that the heat treatment is preferably performed at a temperature between 60°C and 80°C, even more preferably between 65°C and 75°C. The

heat treatment, for example, may be performed for between 30 minutes and 12 hours (see present specification, page 1, lines 25-28 and page 2, lines 3-6). Thus, the present specification does not teach that these parameters are essential to the practice of the claimed invention.

While it is true that Example 1 in the present specification provides that no spheroid forming activity was found in FCS (fetal calf serum) heat treated at 60°C for up to four hours, there was "spefadel" activity after seven hours incubation at this temperature. However, as long as the number of inoperative embodiments falling within a claim remains relatively low, the inclusion of such embodiments within the claim will not destroy the validity of the claim, as long as those skilled in the art would know how to modify any potential failure to secure something useful. *Atlas Powder Co. v. E.I. du Pont*, 224 USPQ 409 (Fed. Cir. 1984). As noted above, applicant believes that one of ordinary skill in the art would be able to determine which specific combinations of time and temperature would provide a reasonable expectation of success, especially in view of the teachings of the specification as a whole. Thus, it is believed that one skilled in the art could modify the temperature and time parameters to secure something even if there was an inoperative embodiment.

Nevertheless, in the interest of advancing prosecution, applicant notes that claim 11 has been amended to indicate that

the heat treatment is performed at a temperature between 60°C and 80°C for between 30 minutes and 12 hours. Indeed, the outstanding Official Action acknowledged on page 4 that the present specification was enabling for a "produced obtained by the process comprising heating calf serum to a temperature between 60°C and 80°C for between 30 minutes and 12 hours". Claims 3, 5-11 and 23 are dependent on claim 1.

As to claim 24-28 and 34-35, applicant notes that claim 24 is a product claim which is directed to a polymeric protein comprising a polymer of one or more proteins contained in fetal calf serum, having molecular weight in excess of 2 MDa and having a spheroid forming activity.

At this time, the Examiner is respectfully reminded that, as long as the specification discloses at least one method for making and using the claimed invention, then the enablement requirement of 35 USC 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 USC 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ 2d 1737, 1743 (Fed. Circ.), cert. denied, 484 US 954 (1987).

Applicant believes that the specification discloses at least one method for making the claimed product. Indeed, as noted above, the Office Action even acknowledges that the present specification is enabling for a product obtained by the process

comprising heating fetal calf serum to a temperature between 60°C and 80°C for between 30 minutes and 12 hours. As a result, applicant believes that the present disclosure is enabling for the claimed polymer

Applicant therefore submits that the breadth of the claims are supported by the disclosure and are representative of the nature of the invention. Performing the methodology set forth in the present disclosure, one skilled in the art would, predictably, arrive at the claimed invention.

In view of the above, applicant respectfully requests that the enablement rejection be withdrawn.

Claims 23 and 26-28 were rejected for allegedly being indefinite and not satisfying the requirements of 35 USC 101. In imposing the rejection, the Official Action alleged that the claims were directed to the recitation of a "use", without setting forth any steps involved in a process. However, claims 23 and 26-28 have been amended to recite method claims. As a result, applicant believes that these rejections have been obviated.

In view of the present amendment and the foregoing Remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

Philip A. DuBois
Philip A. DuBois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/fb